JUL 05 2013

Section 5.0

510(k) Summary

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Pursuant to 21 CFR 807.92c

Submitted By: Thanh Truong
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Date: 6/26/13

Device Information:

Trade Name: Transcorp ACIF System
Common Name: Intervertebral Body Fusion Device
Classification: 21 CFR Section 888.3080, Product Code ODP, Class II

Predicate Devices:

K092794: Transcorp ACIF System
K081730: Alphatec Novel Spinal Spacer System
K090064: Eminent Spine Interbody Fusion System

Device Description:

The proposed modified Transcorp Anterior Cervical Intervertebral Fusion (ACIF) System includes various size implants manufactured from implant grade Solvay Zeniva ZA-500 PEEK conforming to ASTM F2026-08. The implant is hollow to allow for autogenous bone graft material. The implant is provided non-sterile.

Intended Use:

The Transcorp ACIF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. Transcorp ACIF implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autogenous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation.

Proposed Modification:

The subject of this submission includes modification to the geometry of the Intervertebral Body Fusion Devices (IBFDs) and the instruments of the Transcorp ACIF System.

Performance Data:

Performance testing was performed on the proposed modified IBFD. Static and dynamic axial compression, static and dynamic compression shear, and static torsion testing per ASTM F2077-11 were performed. Expulsion testing was also performed on the proposed modified IBFD. Engineering analyses were conducted to evaluate the Subsidence and Wear of the proposed modified implant. No clinical testing was performed.

Substantial Equivalence:

The results of non-clinical testing demonstrates that the design, function, intended use, and indications for use of the proposed modified Transcorp ACIF System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Transcorp, Incorporated
% Mr. Thanh Truong
Engineer
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Byron Center, Michigan 49315

July 5, 2013

Re: K121178
Trade/Device Name: Transcorp ACIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 19, 2013
Received: June 19, 2013

Dear Mr. Truong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K121178

Device Name: Transcorp ACIF System

Indications for Use:

The Transcorp ACIF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. Transcorp ACIF implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autogenous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation.

Prescription Use__X__ or Over-the-counter use _____
(per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices